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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/591,048

03/28/2007

Karl-Hermann Schlingensiepen

4052.003

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30448

7590

09/23/2008

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EXAMINER

WOLLENBERGER, LOUIS V

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/591,048	Applicant(s) SCHLINGENSIEPEN ET AL.	
	Examiner Louis Wollenberger	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 23-45 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Preliminary Amendment

Applicant's preliminary amendment to the claims, filed 8/28/06, is acknowledged. With entry of the amendment, claims 23-45 are pending and subject to restriction as follows.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 23-34 and 38-45, drawn to a method for treating cancer, comprising administering at least one oligonucleotide, and to an antisense oligonucleotide and pharmaceutical composition thereof. Election of this group requires further election of a single gene target or single gene target combination from claim 25, 31, 32, 39, 40, and 42; a single antisense oligonucleotide sequence (i.e., SEQ ID NO) from claim 26, 27, 33, 34, 38, 41, and 45; and a single type of cancer from claims 28-30, 39, 42, and 44, as explained below.

Group II, claim(s) 23, 28-30, 43, and 44, drawn to a method for treating cancer, comprising administering at least one active derivative of an oligonucleotide, and to an active derivative of an antisense oligonucleotide thereof. Election of this group requires further election of a single type of cancer from claims 28-30, and 44, as explained below.

Group III, claim(s) 40, drawn to a method for treating cancer, comprising administering a TGF-beta2 binding protein.* Election of this group requires further election of a single type of cancer from claim 39, as explained below.

Group IV, claim(s) 40, drawn to a method for treating cancer, comprising administering a TGF-beta receptor related inhibitor.* Election of this group requires further election of a single type of cancer from claim 39, as explained below.

Group V, claim(s) 40, drawn to a method for treating cancer, comprising administering a Smad inhibitor.* Election of this group requires further election of a single type of cancer from claim 39, as explained below.

Group VI, claim(s) 40, drawn to a method for treating cancer, comprising administering a TGF-beta2 binding peptide.* Election of this group requires further election of a single type of cancer from claim 39, as explained below.

Group VII, claim(s) 40, drawn to a method for treating cancer, comprising administering a TGF-beta antibody.* Election of this group requires further election of a single type of cancer from claim 39, as explained below.

**Note Claim 39 links the inventions of Groups III-VII and will be examined with each group. See below for further explanation.*

Group VIII, claim(s) 35-37, drawn to a process of manufacturing an antisense oligonucleotide, comprising the step of adding consecutive nucleosides and linker.

Group IX, claim(s) 35, drawn to a process of manufacturing an antisense oligonucleotide, comprising the step of cutting said oligonucleotide out of a longer oligonucleotide.

The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features, as evidenced by the descriptions above. Accordingly, Groups I-IX lack unity of invention *a priori*.

Further Elections

Groups I-VII comprise claims to a plurality of different inventions which are not so linked so as to form a single general inventive concept. For example, claims 25, 31, 32, 39, 40, and 42 of Group I specifically claim several different antisense oligonucleotides that differ one from the other by the particular nucleotide sequence contained therein. Accordingly, each sequence is considered to represent a special technical feature unique to the method not shared by any other method. Similar reasoning applies to the different genes targeted by the method, recited in claim 25 and 32, for example. The claims further require treating a number of different

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cancers, each of which represents a separate special technical feature inasmuch as the methods would necessarily be directed to different patient populations.

Accordingly, the claims lack unity of invention *a priori*. Applicant is required to elect one invention from each of the categories listed above for prosecution with the elected group. This is not a species election.

Applicant is advised that with regard to the “and/or” language in claim 25 and 31, for example, Applicant must elect a single gene or a single combination of genes for prosecution on the merits. In the event Applicant elects a single combination, Applicant must also specify the antisense oligonucleotide sequences, if any, that correspond to and are to be examined with said target combination. In the event of an election of a single combination of target genes, the examined method will be one limited to a method of treating cancer comprising administering a combination of antisense oligonucleotides targeted to the elected combination of target genes.

Linked Inventions

Claim 39 link(s) the inventions of Groups III-VIII; claim 23, the antisense inventions of claims 24-34 and 38-45. Claim 24 is a nested linking claim. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s). Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance,

whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Conclusion

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis Wollenberger whose telephone number is (571)272-8144.

The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571)272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Louis Wollenberger/

Examiner, Art Unit 1635

September 17, 2008